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09/544,341	04/06/2000	Kevin A. Mansmann, M.D.	KM-M1	8036

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EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

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DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

# Office Action Summary

Application No.

C. 544,341

Applicant(s)

MANSMANN, M.D., KEVIN A.

Examiner

D. VIDUJABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the shorter period will be considered timely.
- If NO period for reply is specified above, the maximum statutory period for reply will be considered to be SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by operation of law, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 2 Apr 2012.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is **not** final.
- 3) ☐ Since this application is in condition for patent except for formal matters, prosecution as to the merits is closed in accordance with the practice under 37 CFR 1.102, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction or objection requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required only in this communication.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority document have been received.
2. ☐ Certified copies of the priority document have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority document have been received in this National Stage application from the International Patent Office (IPO) under 37 CFR 1.2(a).
- \* See the attached detailed Office action for information if certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language version of the priority application has been received.
- 15) ☐ Acknowledgment is made of a claim for priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-893)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No. \_\_\_\_\_
- Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- Notice of Informal Patent Application (PTO-152)
- Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a membrane segment, does not reasonably provide enablement for a membrane segment which is not permeable to surface active phospholipids and a pore structure which causes the membrane to interact with hyaluronate and surface active phospholipid molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification discloses a semipermeable membrane but fails to disclose the structure or known membrane which allows the membrane to function as claimed. Clearly, semi permeable membranes are well known. Examiner believes that semi permeable membranes that are selective to low molecular weight nutrients could be known in the art as being dependent on the pore size or polar nature of the of the material. However, it is not clear from the specification that a membrane selective to omit surface active phospholipids is readily known in the art. Therefor with the specification lacking in the descriptive nature of the membrane, it is not clear if one with ordinary skill in the art could make and use this invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as worded is confusing. It is not clear what applicant intends to be the metes and bounds of the claim. Is applicant attempting to positively claim a packaged membrane segment.

Recitation of "is suited in all respect for implantation" is indefinite. The scope of "in all respect" is not readily apparent. Nor is the limitation properly supported by the specification.

Step c is redundant to the same limitation as previously set forth in line 4 of the claim.

Claim 2 is indefinite. The preamble of claim 1 is directed to a membrane segment and claim 2 is directed to either a method of securing the membrane to a scaffold or the combination of the scaffold and the membrane. In either case, the scope of the claim is beyond the metes and bounds of the preamble of claim 1.

Claim 3 is indefinite. It is not clear what encompasses the limitation "designed to be trimmed and secured directly onto".

Claim 8 is indefinite. It is not clear what encompasses the step of a "surface treatment...in a manner".

Claim 9, is indefinite for failing to set forth steps to support the method of repairing.

Claim 12, see rejection as outlined in claim 1 supra. There is no support in the specification for the limitation of compounds having MW greater than 5000 daltons.

Claim 13 fails to set forth a transition phrases that sets up the body of the claim. Therefore, "wherein" should be replaced by --comprising--. Moreover, the claims fail to positively claim the matrix in the body of the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,7-13 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pachence, et al (6080194).

Claims 1-8 are directed to a membrane. Examiner has interpreted the claims as being directed to the membrane and not to any combination of the membrane with associated packaging.

Pachence, et al discloses a collagen membrane that is used in combination with a matrix to repair cartilage defect. The membrane allows movement of fluids, nutrients,

cytokines and other factors required for regeneration. Since the membrane is similar in nature to that as disclosed by applicant, examiner maintains that the membrane of Pachence, et al will function in a manner similar to that as claimed by applicant, including the non-permeability to phospholipids.

The membrane of Pachence, et al is used for in vivo applications. The membrane is planar and therefor has two surfaces, one for placement with a condyle and the other to be exposed as an articulating surface. The surface of the collagen membrane has an average pore sizes greater than 100 microns for growth of chondrocytes thereof and the membrane itself has a thickness of 50-200 microns. Applicant's specification is lacking to the particulars of the membrane that is specific for the function directed to hyaluronate and phospholipid molecules interaction. The claim stand rejected over Pachence, et al since it appears that the material and function of Pachence, et al would inherently sustain similar interaction with hyaluronate and phospholipids.

Claim 2, see the combination of the collagen matrix and the membrane of Pachence, et al (Examples 1-4).

Claim 3, the material of the membrane of Pachence, et al can be trimmed.

Claim 4, see example 2.

Claim 7, see example 3, 4<sup>th</sup> paragraph.

Claim 8, see membrane thickness in column 4, lines 44+.

Claim 9 is directed to a method for implanting the membrane of claim 1. The claim only contains one active step including implanting the membrane onto a defect. This step is clearly disclosed by Pachence, et al. See figure 4.

Claims 10 and 11, see example 4.

Claim 12 fails to distinguish over the membrane of Pachence, et al.

Claim 13 fails to distinguish over the matrix of Pachence, et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pachence, et al as applied to claim 1 (above) and further in view of Moya (5629084).

The use of hydrophilic material in the manufacturing of membranes is known to be old as taught by Moya. To use a hydrophilic membrane in place of the collagen membrane of Pachence, et al in order to increase the hydrophilic nature of the collagen membrane for more selective fluid permeability therethrough would have been obvious from the teachings of Moya.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVIL ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3580 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
DAVID USABELLA  
Primary Examiner  
Art Unit 3738

dji  
May 27, 2003